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6 510(k) Summary

Name of Firm:	Depuy Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Stacey Bonnell Senior, Regulatory Affairs Specialist – Depuy Synthes Spine Telephone: 610-719-5895 Facsimile: 610-719-5102 Email: bonnell.stacey@synthes.com
Date Prepared:	January 18, 2013
Trade Name:	Synthes Synflate Vertebral Balloon System
Classification:	Orthopaedic and Rehabilitation Devices Panel Class II
	21 CFR 888.1100 – Arthroscope, Orthopedic Class II; Product Code HRX
	21 CFR 888.3027 - Cement, Bone, Vertebroplasty Class II; Product Code NDN
Predicate Devices:	Synthes Vertebral Body Balloon (VBB) System (K110604) Kyphon KyphX Xpander Inflatable Bone Tamp (K041454)
Device Description:	The Synflate Vertebral Balloon System is a comprehensive array of instrumentation (Vertebral Access Kit as well as a Biopsy Kit), vertebral augmentation balloons (inclusive of balloon-catheter, stiffening wire, and syringe with luer lock), and Inflation System (previously cleared via K110604). All instruments and implants are provided sterile and packaged separately. The Synflate balloon catheter includes a stiffening wire and syringe with luer lock. The balloon is inflated within the vertebral body via the Inflation System. The Synflate balloon catheter is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.
Intended Use / Indications for Use:	The Synflate Vertebral Balloon System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

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Comparison of the technological characteristics of the device to the predicate device:	The design features, material, and indications for use of the Synflate System are substantially equivalent to the predicate devices identified. Additionally, the safety and effectiveness of this system is adequately supported by documentation within this premarket notification.
Performance Data (Non-clinical and/or Clinical)	Mechanical and biomechanical testing was performed in order to provide data to support a substantial equivalence determination. These tests were performed to characterize the properties and functionality of the Synflate System, as well as to allow comparison with established acceptance criteria. Mechanical and biomechanical testing was performed to assess balloon pressure and volume limitations, burst characteristics, and ability of the device to be used for the reduction of fractures and/or creation of a void in cancellous bone. The conclusions drawn from testing demonstrate that the Synflate System is as safe and effective as the predicate devices identified. Clinical data was not needed to demonstrate the safety and effectiveness of this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2013

Depuy Synthes Spine
% Ms. Stacey Bonnell
Senior Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K130146
Trade/Device Name: Synthes Synflate Vertebral Balloon System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: March 26, 2013
Received: March 27, 2013

Dear Ms. Bonnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use Statement

510(k) Number: _____

Device Name: Synthes Synflate Vertebral Balloon System

Indications for Use:

The Synflate Vertebral Balloon System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130146